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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,297	02/13/2002	Masako Yajima	219451US0	3488

22850 7590 03/28/2007

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/28/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/073,297	YAJIMA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-26 and 33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-26 and 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20070319*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS, IDS AND STATUS OF THE CLAIMS

2. The amendment, remarks and information disclosure statement (IDS) and Form PTO-1449 filed 12/18/06 are acknowledged, entered and considered. In view of Applicant's request claims 9, 15 and 21 have been amended, claims 27-32 have been canceled and claims 33-41 have been added. Claims 9-26 and 33-41 are now pending in the application. The rejections under 35 U.S.C 112, first paragraph and 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's amendment, remarks and cancellation of claims filed 12/18/06. However, the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are maintained for the same reasons discussed in the previous Office action.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. § 102(b) AND 35 U.S.C. 103(a)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 15 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nitsche (U.S. Patent No. 5,240,909).

Claims 10-14, 16-20, 22-26 and newly submitted claims 33-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsche (U.S. Patent No. 5,240,909).

It is noted that Applicant traversed the rejections of the claims (i.e. claims 9-26 and 33-41) under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) over Nitsche together. Thus, the Examiner responds to Applicant's traversal accordingly.

Applicant's arguments filed 08/14/06 have been fully considered but they are not persuasive. Applicant has argued that Nitsche ('909) patent describes administering

lactoferrin to inhibit endotoxins (see Abstract). The reference fails to disclose or suggest administering human-type lactoferrin to a person prior to infection by bacteria, which produce lipopolysaccharide. In fact, in the *in vivo* tests described in Examples 3 and 4 of Nitsche, bacteria were inoculated before administration of lactoferrin. Nitsche certainly fail to suggest the striking experimental results set forth in the specification of the present application discussed above, and as such the rejections under 102(b)/102(a) should be withdrawn is unpersuasive

Contrary to Applicant's arguments the '909 patent of Nitsche discloses the administration of an effective amount of hLf or animal Lf **as an active agent for suppressing inflammation caused by endotoxin LPS-derived from gram-negative bacteria**. Thus, clearly showing the administration of lactoferrin prior to bacterial invasion to suppress inflammation (See Example 1). With respect the limitation of claim 21, which states that wherein, said symptom is decrease of albumin concentration in blood. As disclosed on lines 61-65 at col.12 and as stated previously the above conditions/situations are natural occurrence due to the inflammation, and as such it is inherent property of lactoferrin administration to alleviate the symptoms of such condition/situation. Furthermore, as acknowledged by Applicant on page 2, paragraph 2 in the instant specification, it is known in the art that during sepsis caused by gram-negative bacilli, decline in blood albumin concentration, decrease of lymphocytic leukocytes, and increase of neutrophil occur. Also, on page 4, Applicant acknowledges that bovine-type lactoferrin has been used to demonstrate an effect of alleviating various symptoms, which appear after infection. Thus, albumin exudation at the

inflammatory site or decrease of albumin concentration in blood at the inflammatory site, these are expected natural occurrence during inflammation whatever the cause of inflammation is. Moreover, in view of *In re Sussman*, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), the claims are rejected under 35 U.S.C. 102(b) "that since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." Applicant is claiming an invention employing the **same process steps** but the product(s) is (are) **alleged to be different**. Applicant is required to recite the missing steps to form the alleged different product(s) in view of the above citation. Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 9, 15 and 21 as drafted and renders claims 10-14, 16-20, 22-26 and 33-41 obvious for the reasons discussed under 35 U.S.C. 103(a) rejection in the previous Office action.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

5 No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AAM/Mohamed/AAM
March 19,2007

JON WEBER
SUPERVISORY PATENT EXAMINER